

In the Claims

1. (Currently Amended) A tablet form of a pharmaceutical preparation comprising,

50 - 90% of a pharmacologically acceptable salt of dicholoromethylene biphosphonic acid as an active agent; and
5 - 25% of silicified microcrystalline cellulose, wherein said tablet form is not coated with a film forming agent.

2. (Cancelled)

3. (Previously Presented) The preparation according to claim 1, comprising:

- a) from about 60 to 80% by weight of anhydrous disodium clodronate;
- b) from about 8 to 20% by weight of silicified microcrystalline cellulose; and
- c) from about 0.5 to 10% by weight of lubricants and/or disintegrants.

4. (Previously Presented) The preparation according to claim 1 or 3 wherein silicon dioxide is present in the silicified microcrystalline cellulose in an amount of from about 0.1 to 20% weight, based on the weight of the microcrystalline cellulose.

5. (Cancelled)

6. (Previously Presented) The preparation according to claim 1 or 3, wherein the salt of dichloromethylene biphosphonic acid is the disodium salt.

7. - 10. (Cancelled)

11. (Currently Amended) A pharmaceutical preparation, comprising,

a pharmaceutically acceptable salt of dicholoromethylene biphosphonic acid, and

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an excipient, said excipient comprising silicified microcrystalline cellulose obtained by coprocessing microcrystalline cellulose with from about 0.1 to about 20% silicon dioxide, based on the amount of microcrystalline cellulose, to form an agglomerate of microcrystalline cellulose and silicon dioxide wherein the microcrystalline cellulose and silicon dioxide are in intimate association with each other and the silicon dioxide is integrated with the microcrystalline cellulose particles, but there is no chemical interaction between the two materials, wherein said pharmaceutical preparation is not coated with a film forming agent.

12. - 13. (Cancelled)

14. (Previously Presented) The process of claim 11 wherein

the coprocessing is performed by spray-drying.

15. (Currently Amended) A method of manufacturing a pharmaceutical preparation according to claim 1, comprising:

mixing dry granules of a pharmacologically acceptable salt of dicholoromethylene biphosphonic acid with stearic acid;

sieving said granules;

mixing said granules with croscarmellose sodium, silicified microcrystalline cellulose and magnesium stearate to form a mixture; and

forming tablets from said mixture in a tabletting apparatus apparatus; and optionally coating said tablets with a coating solution.

16. (Currently Amended) A method of manufacturing a pharmaceutical preparation according to claim 1, comprising:

mixing dry granules of a pharmacologically acceptable salt of dicholoromethylene biphosphonic acid with stearic acid in an ethanol solution;

drying and then sieving said granules;

mixing said granules with croscarmellose sodium, silicified microcrystalline cellulose and magnesium stearate to form a mixture; and

forming tablets from said mixture in a tabletting apparatus apparatus; and optionally coating said tablets with a coating solution.

17. (Previously Presented) The process of claim 15 or 16 wherein the silicified microcrystalline cellulose is prepared by coprocessing microcrystalline cellulose with silicon dioxide wherein the microcrystalline cellulose and silicon dioxide are in intimate association with each other and the silicon dioxide is integrated with the microcrystalline cellulose particles, but there is no chemical interaction between the two materials.

18. (Previously Presented) The process of claim 17 wherein microcrystalline cellulose is coprocessed with from about 0.1 to about 20% silicon dioxide, based on the amount of microcrystalline cellulose.
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19. (Previously Presented) The process of claim 17 wherein the coprocessing is performed by spray-drying.

20. (New) A tablet form of a pharmaceutical preparation consisting essentially of:

50-90% of a pharmacologically acceptable salt of dicholoromethylene biphosphonic acid as an active agent;
5-25% of silicified microcrystalline cellulose; and
0.5-10% by weight of lubricants and/or disintegrants.

21. (New) A tablet form of a preparation consisting essentially of:

from about 60 to 80% by weight of anhydrous disodium clodronate;

from about 8 to 20% by weight of silicified microcrystalline cellulose; and

from about 0.5 to 10% by weight of lubricants and/or disintegrants.

22. (New) A pharmaceutical preparation, consisting essentially of:

a pharmaceutically acceptable salt of dicholoromethylene biphosphonic acid, and

an excipient, said excipient comprising silicified microcrystalline cellulose obtained by coprocessing microcrystalline cellulose with from about 0.1 to about 20% silicon dioxide, based on the amount of microcrystalline cellulose, to form an agglomerate of microcrystalline cellulose and silicon dioxide wherein the microcrystalline cellulose and silicon dioxide are in intimate association with each other and the silicon dioxide is integrated with the microcrystalline cellulose particles, but there is no chemical interaction between the two materials.

23. (New) A tablet form of a pharmaceutical preparation consisting of:

50-90% of a pharmacologically acceptable salt of dicholoromethylene biphosphonic acid as an active agent;

5-25% of silicified microcrystalline cellulose; and
0.5-10% by weight of lubricants and/or disintegrants.

24. (New) A tablet form of a preparation consisting of:
from about 60 to 80% by weight of anhydrous disodium clodronate;
from about 8 to 20% by weight of silicified microcrystalline cellulose; and
from about 0.5 to 10% by weight of lubricants and/or disintegrants.

25. (New) A pharmaceutical preparation, consisting of:
a pharmaceutically acceptable salt of dicholoromethylene biphosphonic acid, and
an excipient, said excipient comprising silicified microcrystalline cellulose obtained by coprocessing microcrystalline cellulose with from about 0.1 to about 20% silicon dioxide, based on the amount of microcrystalline cellulose, to form an agglomerate of microcrystalline cellulose and silicon dioxide wherein the microcrystalline cellulose and silicon dioxide are in intimate association with each other and the silicon dioxide is integrated with the microcrystalline cellulose particles, but there is no chemical interaction between the two materials.

26 (New) A tablet form of a pharmaceutical preparation,

comprising:

50 - 90% of a pharmacologically acceptable salt of dicholoromethylene biphosphonic acid as an active agent; and
5 - 25% of silicified microcrystalline cellulose,
wherein said tablet form is not coated with an enteric coating.
